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K081565

JUL - 2 2008

Attachment 5: 510(k) Summary

***Submitter's Name:**	Ellex Medical Pty. Ltd. **Manufacturing and packaging.*
Submitter's Address:	82 Gilbert Street Adelaide, South Australia, 5000 AUSTRALIA
Contact Person:	Kevin Howard, Senior Regulatory Officer
Contact Details:	Tel +61 8 8104 5200 Fax +61 8 8221 5645 Email: khoward@ellex.com
Date Summary Prepared:	May 27, 2008
Trade Name of Modified Device: (For which this Special 510(k) is being submitted)	Integre Pro
Common Name of Modified Device: (For which this Special 510(k) is being submitted)	Photocoagulator Ophthalmic Laser
Classification of Device:	Class II, HQF; GEX, Ophthalmic Laser
Trade Name of Predicate Device:	Ellex Integre Duo LP1RG
Common of Predicate Device:	Photocoagulator Ophthalmic Laser
Classification of Device:	Class II, Ophthalmic Laser
Description of the Device:	The Integre Pro L2RY is an addition to the Ellex range of ophthalmic photocoagulators. The Integre family are designed for use by ophthalmologists in a clinic or outpatient facility, or in the Retinal Specialist's office. It is capable of producing focused pulses of red or yellow light with wavelengths of 670 nanometres (nm) and 561 nm respectively. The red and yellow beams may be used for the same treatments, but the red gives increased penetration of haemorrhaging tissue and fluids, and may also be used to treat ocular melanomas. The Integre Pro L2RY is based upon the Integre Duo LP1RG with a modification to the laser cavity optical components which results in a yellow (561 nm) treatment laser output.

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The principle reasons for modifying the current model Integre Duo and creating the Integre Pro are for the following;

- Clinical versatility. That is, being able to offer most treatment capabilities with just two clinically proven wavelengths, red and yellow with sufficient power to treat not only the macular but also wherever green laser is indicated.
- Fully integrated design platform
- Flexibility, integrated design but still allows for adaption to a variety of slit lamps and delivery systems

As with the Integre Duo, the laser pulses are accurately positioned on a structure within the patient's eye with the aid of a delivery device. The delivery device is an integrated slit-lamp microscope. An optional Laser Indirect Ophthalmoscope (LIO) can also be used.

Intended Use:

The Integre Pro is an ophthalmic photocoagulator laser designed to be used by ophthalmologists for treatment of ocular pathology of the eye. It has identical intended uses as the previously cleared Integre Duo LP1RG, 510(k) K052777 and Integre LP561, 510(k) K080423.
The Indications for Use statement can be found in **Attachment 2**

Comparison of Technological Characteristics:

Refer to the following tables for a comparison of the Integre Pro with the Integre Duo LP1RG and other commercially available predicate devices

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Comparison Table – Treatment lasers of devices

Characteristic compared	Ellex Integre Pro L2RY	Ellex Integre Duo LP1RG; K052777	Ellex Integre LP561; K080423
Laser Type	True CW Diode-Pumped Solid-State (DPSS)	True CW Diode-Pumped Solid-State (DPSS)	True CW Diode-Pumped Solid-State (DPSS)
Laser Wavelength	561 nm (yellow) 670 nm (red)	532 nm (green) 670 nm (red)	561 nm (yellow)
Laser Power	50-1500 mW (yellow) 50-1500 mW (red)	50-2000 mW (green) 50-1500 mW (red)	50-1500 mW (yellow)
Exposure time settings (pulse duration)	0.01 to 4.0 seconds adjustable in variable increments	0.01 to 4.0 seconds adjustable in variable increments	0.01 to 4.0 seconds adjustable in variable increments
Repeat mode intervals	0.1 to 1.0 seconds	0.1 to 1.0 seconds	0.1 to 1.0 seconds
Laser Safety Class	4/IV	4/IV	4/IV
Spot Size	50 to 1000 µm	50 to 1000 µm	50 to 1000 µm

Comparison Table – Aiming lasers of devices

Characteristic compared	Ellex Integre Pro L2RY	Ellex Integre Duo LP1RG; K052777	Ellex Integre LP561; K080423
Aiming Laser Type	Semi conductor laser diode	Semi conductor laser diode	Semi conductor laser diode
Aiming Laser Power	<1 mW	<1 mW	<1 mW
Aiming Wavelength	635 -5/+10 nm	635 -5/+10 nm	635 -5/+10 nm
Laser Safety Class	2/II	2/II	2/II

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Comparison Table – Electrical and Mechanical Characteristics of Devices

Characteristic compared	Ellex Integre Pro L2RY	Ellex Integre Duo LP1RG; K052777	Ellex Integre LP561; K080423
Mains Electrical Supply Voltage	100-240VAC; 800VA	100-240VAC; 800VA	100-240VAC; 800VA
Supply Frequency	50/60Hz	50/60Hz	50/60Hz
Weight	32 kg (un-packed system w/out stand) (proposed)	32 kg (un-packed system w/out stand)	32 kg (un-packed system w/out stand)
Size	Console/table top H100 x W834 x D436 mm (proposed)	Console H123 x W434 x D512 mm	Console H123 x W434 x D512 mm
Operating Temperature Range	+10 C to +40 C; RH 35 to 85%	+10 C to +40 C; RH 10 to 85%	+10 C to +40 C; RH 10 to 85%
Transport & Storage Temperature Range	-10 C to +55 C; RH 35 to 85%	-10 C to +55 C; RH 10 to 85%	-10 C to +55 C; RH 10 to 85%
Cooling (console)	Air cooled with integrated active thermo-electric cooler (TEC)	Air cooled with integrated active thermo-electric cooler (TEC)	Air cooled with integrated active thermo-electric cooler (TEC)

Comparison Table –Delivery Devices

Delivery Device	Ellex Integre Pro L2RY	Ellex Integre Duo LP1RG; K052777	Ellex Integre LP561; 510(k) K080423
Slit Lamp Delivery System (SDS)	Treatment & aiming lasers integrated into slit lamp microscope or optional slit lamp adaptors.	Treatment & aiming lasers integrated into slit lamp microscope.	Treatment & aiming lasers integrated into slit lamp microscope.
Laser Indirect Ophthalmoscope (LIO)	Ellex LIO.	Ellex LIO.	Ellex LIO.

Comparison Table – Standard Accessories

Accessory	Ellex Integre Pro L2RY	Ellex Integre Duo LP1RG; K052777	Ellex Integre LP561; 510(k) K080423
Footswitch	Collapsible footswitch. Power control footswitch accessory available.	Collapsible footswitch. Power control footswitch accessory available.	Collapsible footswitch. Power control footswitch accessory available.
Remote Control Unit (RCU)	Colour LCD model.	Monochrome LCD model.	Monochrome LCD model.
Safety Filter	Fixed eye safety filter. Moveable eye safety filter as an accessory.	Moveable eye safety filter.	Moveable eye safety filter.
Table/stand	Integrated table and stand	Choice of Ellex Total Solution Stand	Choice of Ellex Total Solution Stand

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Comparison - Indications for Use of Devices

Ellex Integre Pro L2RY	Ellex Integre Duo LP1RG; K052777	Ellex Integre LP561; K080423
Photocoagulation of both anterior & posterior segments of the eye including: • Retinal photocoagulation & pan retinal photocoagulation of vascular & structural abnormalities of the retina & choroid including: - proliferative & nonproliferative diabetic retinopathy; - choroidal neovascularization; - branch retinal vein occlusion; - age-related macular degeneration - retinal tears & detachments - retinopathy of prematurity • Iridotomy, iridectomy, suturelysis & trabeculoplasty in angle closure glaucoma & open angle glaucoma	Photocoagulation of both anterior and posterior segments of the eye including: •Retinal photocoagulation & pan retinal photocoagulation of vascular & structural abnormalities of the retina & choroid including: - proliferative & nonproliferative diabetic retinopathy; - choroidal neovascularization; - branch retinal vein occlusion; - age-related macular degeneration - retinal tears & detachments - retinopathy of prematurity • Iridotomy, iridectomy, suturelysis & trabeculoplasty in angle closure glaucoma and open angle glaucoma	Photocoagulation of both anterior & posterior segments of the eye including: • Retinal photocoagulation & pan retinal photocoagulation of vascular & structural abnormalities of the retina & choroid including: - proliferative & nonproliferative diabetic retinopathy; - choroidal neovascularization; - branch retinal vein occlusion; - age-related macular degeneration - retinal tears & detachments - retinopathy of prematurity Iridotomy, iridectomy, suturelysis & trabeculoplasty in angle closure glaucoma & open angle glaucoma

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Conclusion:

Ellex Medical has demonstrated by its evaluation of the Integre Pro L2RY that modification to the predicate device, the Integre Duo LP1RG, does not adversely affect the intended use, technological characteristics or safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2008

Ellex Medical Pty. Ltd.
c/o Kevin Howard, Senior Regulatory Officer
82 Gilbert Street
Adelaide, South Australia, 5000
AUSTRALIA

Re: K081565
Trade/Device Name: Integre Pro, Model L2
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF
Dated: May 27, 2008
Received: June 4, 2007

Dear Mr. Howard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Attachment 2

Indications for Use Statement

510(k) Number (if known): K081565

Device Name: Ellex Integre Pro L2RY ophthalmic laser.

Indications for Use:

The Integre family of Ophthalmic laser and Delivery Devices are intended to be used in the treatment of ocular pathology.
The Ellex Integre Pro L2RY is indicated for use in photocoagulation of both anterior and posterior segments of the eye including:

- Retinal photocoagulation and pan retinal photocoagulation of vascular and structural abnormalities of the retina and choroid including:
  - proliferative and nonproliferative diabetic retinopathy;
  - choroidal neovascularization;
  - branch retinal vein occlusion;
  - age-related macular degeneration;
  - retinal tears and detachments;
  - retinopathy of prematurity;
- Iridotomy, iridectomy, suturelysis and trabeculoplasty in angle closure glaucoma and open angle glaucoma

Prescription Use X AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bruce Drum

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

Page 1 of____ **510(k) Number** K081565